# Board of Pharmacy

The mission of the Maryland Board of Pharmacy is to protect Maryland consumers and to promote quality health care in the field of pharmacy through licensing pharmacists and issuing permits to pharmacies and distributors; setting standards for the practice of pharmacy through regulations and legislation; receiving and resolving complaints and educating consumers. The Maryland Board of Pharmacy sets standards that ensure safety and quality health care for the citizens of Maryland.



#### Maryland Board of Pharmacy

4201 Patterson Ave. Baltimore, MD 21215-2299 410-764-4755 www.mdbop.org

### **Medication Error Investigations by the Board**

The Board of Pharmacy receives numerous complaints from the public. The vast majority deals with prescription errors and customer service issues. The Disciplinary Committee of the Board works in tandem with the Compliance unit to investigate and resolve these cases.

The current procedure used for investigating medication error complaints from consumers is a direct result of recommendations made by the Medication Error Task Force in 2002. The Task Force recommended and the Board instituted a "systems" approach when handling medication error cases, rather than holding the pharmacist solely responsible for every medication error regardless of the circumstances.

When the Board receives a medication error complaint, the Compliance unit initiates an investigation to obtain information that is needed by the Board to decide the appropriate action to take to insure the safety of the public. First, a determination is made whether or not an error was actually made. If needed, additional information is elicited from the consumer. Second, a letter is sent to the pharmacist (if one is identified) and the permit holder, notifying them of the complaint, along with an Error Data Collection Form (EDCF) that we request to be filled out by the pharmacist and/or the permit holder. The EDCF asks for information about contributing factors, how the error could have occurred, who was involved, what follow-up was done with the patient, and what actions have been taken to prevent the likelihood of this error happening again. The EDCF is a confidential document and is considered part of a Board investigation.

Once the reply from the pharmacist and/or the permit holder is received, the Disciplinary Committee reviews the complaint and the responses, along with information gathered through the EDCF. If the committee needs more information, the compliance unit will continue the investigation. When the Committee feels it has sufficient information, it will determine what action, if any, it will recommend to the Board. The actions that can result from a complaint include:

- 1. Letter of Education (informal, nonpublic action). This is an educational letter directed at improving the medication safety procedures of the pharmacist/ permit holder.
- 2. Letter of Admonishment (informal, nonpublic). This letter contains a determination that the pharmacist/permit holder committed a violation, usually a minor violation, and generally requires the pharmacist/permit holder to engage in certain educational or remedial measures in order to resolve the matter.
- **3. Formal Disciplinary Action.** The Board issues charges against the pharmacist and/or permit holder for violation of law. Formal action can lead to fines, probationary restrictions on a license, or suspension/revocation of a license/permit.

The Board is encouraged that most pharmacists and permit holders have taken the time and effort to respond to requests for information in a timely and comprehensive manner. Full cooperation in these matters will obviate the need to subpoena records and require the pharmacist/permit holder to personally appear before the Compliance unit for an investigative interview.

The Board acknowledges that errors can occur even in the absence of negligence or misconduct. However, in keeping with our duty to protect the public, we must ensure that complaints are thoroughly and fairly investigated and that measures are put in place to minimize the reoccurrence of a similar incident.

### Board of Pharmacy Bio-terrorism and Emergency Preparedness

To become a volunteer of the "Maryland Pharmacists Volunteer Corps" visit the Board's web site at www.mdbop. org and register or contact Joan Lawrence, at (410) 764-4755, email: rxemergency@dhmh. state.md.us.

### Let Us Know How We Are Doing...

Please e-mail your questions, concerns or comments to us at the following e-mails. We value your feedback. *General*—E-mail Joan Lawrence at: jlawrence@ dhmh.state.md.us

### Address or Employment Change

Submit the Pharmacist Change of Information form on our web site. Go to: www.mdbop.org and click on Forms & Publications.

# From the Executive Director's Desk

My commentary in this issue is dedicated to Stanton G. Ades, Board President, Wayne Dyke, Chair of the Board Licensing Committee and Reverend William Johnson, Board Consumer Representative. Each will end their second four-year term on the Maryland Board of Pharmacy in April 2004. Their leaving will significantly change the face and personality of the Board.

residing over all public and executive sessions, administrative hearings, task forces and other formal Board proceedings, President Ades has employed sage understanding, strong leadership and sound diplomacy. Under his tutelage the Board has addressed drug therapy management, patient safety, long term care and assisted living, uniform prescription cards, medical privacy and confidentiality (HIPAA), delivery of prescriptions, quality assurance measures, impoundment of prescription drugs, portable emergency drug kits, electronic licensing, non-prescriptive contact lenses, outsourcing, nurse dispensing, emergency preparedness and a myriad of other issues that were germane to pharmacy practice.

Mr. Dyke was Licensing Committee Chair when I joined the Board four years ago and continues in that position today. He is one of the Board's unsung heroes who quietly provides stellar leadership both to the committee and the Board's Licensing Unit in reviewing applications, determining fees, examining trends that could affect licensing standards, developing and administering examinations, and overseeing the development of the Board's on-line renewal systems.

Reverend William Johnson has been the public guardian on the Board. As Board Consumer member, the Reverend (as he is fondly called) attended as many possible committee and task force meetings to insure that the impacts of Board decisions on Maryland citizens were always considered. Spiritedly meeting his charge (pardon the double-entendre), the Reverend's comments provided insights on issues that may have been otherwise overlooked.

President Ades, Chairman Dyke and Rev. Johnson were each appointed to the Board in 1996. Electronic prescribing, fax transmissions, and automated dispensing were concepts that had not been addressed because use of technology in pharmacy practice was limited. Technology usage is now *very* routine, and under these exiting members' oversight, technology has been addressed through regulation, as well as with the launching of the Board's own web site, and on-line renewal systems.

Some recent changes at the Board of Pharmacy are being celebrated. I am pleased to announce Ms. Shirley Costley as the Licensing Supervisor, and Ms. Marianne S. Pindell who joined the Board of Pharmacy staff replacing Ms. Costley as the Fiscal/Personnel Officer. Ms. Pindell recently retired from the Department of Health and Human Services, Health Care Finance Administration where she had been employed for about twenty years. Her most recent title there was Health Insurance Specialist. In that capacity she procured and tracked contracts, developed and maintained annual budgets, coordinated staff training, performed purchasing and other general office duties. Please join me in welcoming Ms. Pindell as the Board's new Fiscal/Personnel Officer and in thanking Ms. Costley for the fine leadership she provided, and much success in her new position. President Ades, Chairman Dyke and Rev. Johnson will be sorely missed.

# **Automated Medication Systems**

Modern technology has revolutionized pharmacy practice in many ways, including robotic prescription filling, computerized/paperless dispensing and tracking systems, electronic prescribing and the use of automated medication delivery and dispensing systems in health care facilities.

he Board of Pharmacy often gets requests to approve a system used in the distribution/dispensing process. The Board cannot endorse any particular product, but can comment on how the system would have to be used in order to comply with current law. Many questions can be answered by referring to COMAR 10:34.28, Automated Medication Systems, (page 308 of the 2002 edition of Maryland Pharmacy Law Book).

A frequent question to the Board deals with the use of decentralized dispensing units in long-term care settings in acute care hospitals. (Transitional Care or Sub

acute units). The Board of Pharmacy does NOT prohibit the use of this technology when used in accordance with the Automation Regulations and is in a unit where the facility (hospital) has an on-site pharmacy. We remind permit holders, however, that these units are regulated by the Office of Healthcare Quality and are subject to statutes and regulations governing medication delivery and storage in Long Term Care settings.

A newer issue that has been proposed to the Board is the use of automated dispensing of prescriptions in the Emergency Departments of hospitals. Currently, our laws do not recognize "telepharmacy", however, do allow for certain licensed prescribers to dispense, if they have a dispensing permit issued by their respective Board. The practitioner can only dispense to a patient they are personally treating, and must offer a written/printed prescription to the patient to be filled elsewhere if the patient chooses. Please refer to HO.12.102.c (the Pharmacy act), and COMAR 10.13.01 (Dispensing by a licensed prescriber). Also, these systems would be subject to most of the regulations in COMAR 10.34.28 (Automated Medication Systems). In this case, the Physician would be the "final check" of the medication.

# **Legislative/Regulations Updates**

Bills to watch during the 2004 Maryland Legislative Session:

#### **House of Delegates Bills:**

- HB 203–Public Health-Licensed Pharmacists-Dispensing Emergency Contraception
- HB 204–Public Health-Licensed Pharmacists-Emergency Contraception Dispensing Program
- HB 384–Maryland Pharmacy Act-Practice of Pharmacy-Administration of Medication
- HB 397–Pharmacy Benefits Management Act
- HB 433–Prescription Drug Safety Act
- HB 840–Pharmacy Benefits Managers
- HB 998–State Board of Pharmacy-Registration of Pharmacy Technicians
- HB 1143–Prescription Drug Distribution Safety Act

#### **Senate Bills:**

- SB 167-Prescription Drugs-Canadian Mail Order Plan
- SB 247–Public Health-Licensed Pharmacists-Dispensing Emergency Contraception
- SB 248–Public Health-Licensed Pharmacists-Emergency Contraception Dispensing Program
- SB 389–Maryland Pharmacy Act-Practice of Pharmacy-Administration of the Influenza Vaccination

To access these bills, log on to the Maryland General Assembly's web site at www.mlis.state.md.us. Once on the web site, click "Bill Information and Status." Type the bill number into the query slot.

### **License Renewal Process**



Is your pharmacy renewal date close? Check out the Board's web site at www.mdbop.org and click "Renew Online."

ake a minute to look in your wallet or purse to see if your pharmacy license renewal date is close or -horrorspast! Just as the Motor Vehicle Administration expects a driver to renew his/her license even if the driver did not receive (or did not realize that they received) the notification of his/her renewal date, the Maryland Board of Pharmacy expects pharmacists to know that their renewal date is impending.

Maryland law requires that the Board send one renewal notice at least one month before your license expires, to your last known address. That last part is important since pharmacists are required by law to notify the Board of address changes within 30 days of a move. The Board cannot be held responsible for mail not being received by you either because you have not reported your new address, or for any other reason the mail does not get to you.

In practice, however, the Board sends a first notice 45-60 days prior to expiration, and usually sends a reminder notice about 30 davs later. As a last resort, a letter is sent as soon as possible after the expiration date for pharmacists who have not renewed or notified the Board of intent not to renew. If a pharmacist has not renewed by this time, the pharmacist cannot be practicing pharmacy and will have to reinstate an expired license by meeting reinstatement requirements, based on the length of time that the license has been expired (See C.O.M.A.R. 10.34.13.03), and pay an additional fee.

A reminder for pharmacists who are also practicing in other states or who intend to in the future – You must retain an active license in a state in which you were licensed by examination if you expect to reciprocate to yet another state. All reciprocations go through the original state of licensure by examination.

Pharmacists who have not obtained the required continuing education credits may request an extension of time beyond the expiration date of their license, but CANNOT practice pharmacy until the CE requirement is met.

Please give the Board ample time to process your application so that you can receive your renewed license before your current license expires. If your application is received more than 14 days prior to expiration, you may practice beyond the expiration date if for some reason the Board cannot get the license to you. However, State law mandates that if an application is received 14 days or less before the expiration date, an individual may NOT practice his/her profession until they receive their license from the Board. Although every attempt is made to send your renewed license in a timely manner, if you wait until the last minute to renew, the Board cannot guarantee that you will not have a lapse in licensure.

Remember, pharmacists may also renew their licenses on-line within 60 days prior to their renewal expiration date. For more information about this option, visit the Board's web site at www. mdbop.org and click on 'Renew Online.'

The message then, is twofold: Check your wallet card to be sure your license does not expire shortly, and apply for renewal early, even if you use the online process. ■

# Long Term Care (LTC)

The Long Term Care (LTC) Task Force has completed the initial phase of its charge from the Board, to review and recommend revisions to the current regulations covering pharmaceutical services to residents in long-term care facilities. The task force submitted its draft regulations to the Board for approval at the January monthly meeting. The approved regulations will soon be published for comment in the Maryland Register.

The LTC Task Force has been working in conjunction with the Board of Pharmacy Practice Committee for the past eighteen months. Their combined effort has produced regulations that address current marketplace practices. A comprehensive section on packaging represents the most noteworthy change from prior regulations. During the coming months, the task force is focusing on pharmaceutical services in assisted living facilities. The present regulations for pharmacy services do not adequately address assisted living and are the focus of several other regulatory entities. The Office of Health Care Quality, which license assisted living facilities, is interested in the work of the task force and has been assisting in the effort. Medication management, physician oversight, pharmacy consultation, and the prescription ordering process for patients in assisted living facilities are currently under review by the task force.

The task force consists of Board of Pharmacy Commissioners John H. Balch, Chair, Stanton G. Ades, and Donald Yee. Representatives of the long-term care industry include Bruce Krug, Arnold Clayman, Mayer Handel-



During the coming months, the task force is focusing on pharmaceutical services in assisted living facilities.

man, Nancy Lande, and Arthur Riley. James Slade, Legislative/Regulations Officer; LaVerne Naesea, Executive Director; Catherine Putz, Compliance Officer, and Sandra Hines, Administrative Assistant, represent the Board of Pharmacy staff. Meetings are held the third Tuesday of every month and

will continue until all segments of long-term care have been reviewed. Anyone interested in contacting the Long Term Care Task Force may call Catherine Putz, Compliance Officer at the Board of Pharmacy by calling 410-764-4756 or by utilizing the Board's web site: www.mdbop.org.

### **Mark Your Calendars** Join the Board of Pharmacy and the Maryland Pharmacy Coalition, Wednesday, May 12th at the 87th Annual Spring Flower Mart

The Board of Pharmacy and the Maryland Pharmacy Coalition [which consists of Maryland Pharmacists Association (MPhA), Maryland Society of Health System Pharmacists (MSHP), Maryland Chapter of the American Society of Consultant Pharmacists (MD-ASCP) and Maryland Pharmaceutical Society (MPhS)], will jointly participate in the City of Baltimore's 87th Annual Spring Flower Mart, Wednesday, May 12, 2004 (rain date May 13), at the Washington Monument in Mount Vernon Square.

There will be two booths in the Health Village, and we are asking for pharmacists and pharmacy student volunteers to work 1-2 hours (11:00 a.m. – 6:00 p.m.) to answer consumer questions about medications, interactions and to distribute material. John Balch, Board Member/PharmaCare, will again donate a magnificent wreath to raffle for those who received blood pressure screenings.

If you would like to volunteer at the Flower Mart please contact your pharmacy association or the Board of Pharmacy, attention Joan Lawrence, 410-764-4755 or email jlawrence@dhmh.state.md.us and sign up. ■

### **Frequently Asked Questions**

In day–to–day pharmacy practice, unusual situations sometimes occur generating questions. So to help out licensees, "Frequently Asked Questions" will be featured in each issue of the Board's newsletter. If you have any questions you would like to see answered in this column, please fax your question to 410-358-6207 or email Joan Lawrence at jlawrence@dhmh.state.md.us.

### Compliance

- Q: I work in a pharmacy that employs a number of pharmacists and I have become aware that one of the pharmacists is dispensing prescription drugs to friends and family members without prescriptions. The "prescriptions" are written on phone-in blanks using a hospital's name as the prescriber and are paid for in cash. It is a busy high volume store, and I don't have the time nor do I want to get involved in what may not be my business. However, I am concerned and I don't want to get in trouble or cause problems, but I want to know if I have an obligation to do something. Please advise me.
- A: This is not only an ethical issue for you, but the Code of Maryland Regulations (COMAR) does address this issue in "Duty to Report 10.34.10.05" which states that "a pharmacist shall report to the Board:
  - Conduct which violates a statute or regulation pertaining to the practice of pharmacy;
  - Conduct by a pharmacist that deceives, defrauds, or harms the public; and
  - 3) The unauthorized practice of pharmacy."

The Board appreciates the situation that may exist if you report a coworker. While the Board does not encourage anonymous complaints, it will act upon anonymous complaints if that complaint can be collaborated by other means.

This section of COMAR also states that "a pharmacist shall report to the pharmacist rehabilitation committee (PEAC) conduct by a pharmacist that involves drug or alcohol abuse or dependency." You'll be doing the pharmacist and the community a favor when you call PEAC at 410-452-8683 or e-mail them at peac@bellatlantic.net to report issues with drugs or alcohol. All referrals are kept confidential and are not reported to the Board. The impaired pharmacist is given the opportunity to recover, and lives are saved. It is a difficult decision and many pharmacists are unsure of their obligation. Please call PEAC if you or a pharmacist that you know has problems with drugs or alcohol that are interfering with the practice of pharmacy. THERE IS HELP!

- Q: How long is a prescription for a Controlled Dangerous Substance (CDS) valid?
- A: Health Occupations, HO 12-503, requires the authorized prescriber to "indicate on the prescription the date of its issuance." Unless the prescriber indicates otherwise, the pharmacist "may not dispense any drug or devise on a prescription presented more than 120 days after the date the prescription was issued." Reimbursement plans may have differing limitations. Medical Assistance allows a 30-day time period for filling all CDS prescriptions. Additional information regarding Medicaid prescriptions can be obtained by calling Maryland Pharmacy Program at 410-767-1455. However, pharmacists can obtain permission from prescribers to "update" Schedules III to V prescriptions and document the date change on the prescription. The original prescribing date may not be changed on a prescription for a Schedule II product. It is always recommended that pharmacists also use their professional judgment regarding time limitations on prescriptions especially when dispensing controlled substances.

- Q: After a technician manually fills a drug cart in a hospital can another technician check the work of that technician? In other words can a "tech check tech" system be used?
- A: No, pharmacists are required to check technician's work such as cart filling. However, systems that "possess sufficient safeguards to ensure accuracy of the replenishment" allow the filling of an automated medication system by personnel supervised by a licensed pharmacist without a final check by the pharmacist. Automated systems employing bar code drug identification systems along with the other requirements listed in the Code of Maryland Regulations concerning Automated Medication Systems (10.34.28) have the necessary safeguards to be included in this category.
- Q: Are prescriptions transmitted by facsimile valid for reimbursement by Medicaid? What about Medicaid prescriptions for controlled substances?
- A: Yes, Medicaid accepts prescriptions transmitted by facsimile. Medical Assistance facsimile prescriptions for controlled dangerous substances have the same State and Federal requirements as any other prescriptions for CDS. Prescriptions for Schedules III to V can be transmitted via fax. For a Schedule II prescription, the facsimile prescription serves as the original written prescription only for the following three exceptions: the prescription is for a patient undergoing home infusion (IV) pain therapy; for patients in Long Term Care Facilities (LTCF); and for a patient in hospice care as certified under Medicare when the practitioner notes on the prescription that it is for a hospice patient.

# **Fast Bytes**

#### Vantin Mix-up

Graham Development Inc, a drug repackaging company, issued a recall on the antibiotic Vantin because some bottles partially contain the heart pill Lanoxin. Vantin is football-shaped, orange-red, and Lanoxin is white and round, making it easy to differentiate the pills. Lot K08210301 is affected, but other lots may also be adulterated. Be sure to open all bottles of Vantin before dispensing and do not just put a label on a full, unopened container. View the full contents.

#### **Acetaminophen Use**

Although serious liver damage from taking acetaminophen is rare, relative to the estimated 100 million people who take acetaminophen each year, 56,000 emergency room visits a year are due to acetaminophen overdoses and about 100 people a year die after unintentionally taking too much, according to FDA. The risk of liver damage increases if you have three or more alcoholic drinks while using the drug, which is an ingredient in more than 600 OTC products and some prescription products such as Darvocet, Percocet and Vicodin.

#### **New Sterile Regulations**

The new U.S. Pharmacopeia, Chapter 797–Pharmaceutical Compounding Sterile Preparations Regulations became effective January 1, 2004 replacing USP Chapter 1206, Sterile Drug Products for Home Use. There are sweeping changes in the rules, including the effect of the re-numbering. Chapters below 1000 in



the USP can be enforced by state boards of pharmacy and in the case of sterile compounding can be used by the FDA to cite when those preparations are contaminated and adulterated.

Some of the changes include:

- Sterile products must be made in an ISO Class 8 room, which is a Class 100,000 clean room
- A quality assurance program must be in place
- Outcomes must be monitored
- Batch records and lot numbers must be used and recorded
- Temperature-sensitive products should be handled properly
- Beyond use dating is the new term for expiration date
- Tests must be conducted on the finished products to ensure that they were made correctly
- Aseptic techniques must be validated for each person involved in the process

For complete information including explanations of the above summaries, you can obtain a copy of USP 797 from Lynn Lang at lfl@usp.org or by faxing at (301) 816-8299. ■

# **Upcoming Events**

#### Phase I Training

The Board of Pharmacy and the University of Maryland School of Pharmacy presented "The Pharmacists' Response to Bioterrorism" Phase 1 Training April 17th, 2004. To register as a volunteer call 410-764-4755 or email: rxemergency@dhmh.state.md.us.

#### Flower Mart

Join the Board of Pharmacy and the Maryland Pharmacy Coalition Wednesday, May 12, 2004 at the 87th Annual Spring Flower Mart (rain date May 13), 11:00 a.m. – 6:00 p.m. For more information on volunteering call the Board at: 410-764-4755 or your association.

#### MPhA's 122nd Annual Convention

June 12 – 15th, 2004 Ocean City, Maryland. Theme: Surf, Sand and CE. For registration information call 410-727-0746.

#### 11th Annual MD-ASCP

Mid-Atlantic Conference August 5 – 8, 2004, Rocky Gap Lodge & Resort. For registration information call 410-465-9975.

#### 38th Annual MSHP Seminar

October 15-17, 2004, Hyatt Regency At Reston Town Center, Reston, Virginia. For registration information call 410-465-9975.

#### Pharmacists' Education and Assistance Committee (PEAC) Continuing Education Program

"Crossing the Line, When Prescription Drug Use Becomes Abuse and Addiction," October 21, 2004, Ten Oaks Ballroom, Clarksville, Howard County. For registration information call 410-706-7513.

# **Disciplinary Actions**

Lawrence Appel (License# 08351) Effective January 6, 2004, license to practice pharmacy is revoked.

#### Clarence Howard (License# 16421)

Effective January 30, 2004, license to practice pharmacy is summarily suspended.



# **Maryland Board of Pharmacy**

**Board Staff** 

LaVerne G. Naesea-Executive Director

Shirley Costley-Licensing Supervisor Marianne Pindell-Fiscal/Personnel Officer

Bioterrorism Coordinator

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Sandra Hines-Secretary

Latonya Dickerson-Board Secretary

Deitra M. Gale-Compliance Specialist

Vladimir Konstantinov-Database Specialist

Doris James-Licensing Specialist

Jena Greenberg-Data Clerk (Temp)

Tamarra Banks-Information Services Manager

Joan Lawrence-Public Information Manager &

Catherine Putz-Pharmacist Compliance Officer

James Slade-Regulations/Legislative Officer

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Linda Bethman, Board Counsel

### **Contribute Your Ideas**

This newsletter is created to keep you informed, and to cover topics that are of interest to you. If there is a particular topic that would be helpful to you, let us know.

#### Send information to:

Joan Lawrence, Maryland Board of Pharmacy, 4201 Patterson Avenue, Baltimore, MD 21215-2299 or fax/e-mail: 410-358-6207; jlawrence@dhmh.state.md.us.

Feel free to contact the Board staff for assistance with information, questions or concerns.

The services and facilities of the Maryland State Department of Health and Mental Hygiene (DHMH) are operated on a nondiscriminatory basis. This policy prohibits discrimination on the basis of race, color, sex or national origin, and applies to the provisions of employment and granting of advantage, privileges, and accommodations. The department, in compliance with the Americans and Disabilities Act, ensures that qualified individuals with disabilities are given an opportunity to participate in and benefit from DHMH services, programs, benefits, and employment opportunities.

Joan M. Lawrence, Staff Editor; Jeanne Furman, Board Editor; Ramona McCarthy Hawkins, Assistant Board Editor

### **Meetings**

The Pharmacy Board meetings are open to the public 9:00 a.m.– 12:00 Noon at 4201 Patterson Avenue, Baltimore, MD 21215. The Board encourages all interested parties to attend.

#### 2004 BOARD MEETING DATES

Wednesday, April 21, 2004 Wednesday, May 19, 2004 Wednesday, June 16, 2004 Wednesday, July 21, 2004 Wednesday, August 18, 2004 Wednesday, September 15, 2004 Wednesday, October 20, 2004 Wednesday, November 17, 2004

Agendas and other information can be obtained by contacting the Board at 410-764-4755.

#### **Editorial Committee:**

Linda Bethman, Board Counsel Jeanne Furman, Board Member Ramona McCarthy Hawkins, Board Member LaVerne Naesea, Executive Director

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